REMARKS

In Paragraph 11 of the Office Action dated February 11, 2003 the Examiner objected to Claims 5-10 as they depended on another multiply dependent claim. In the Applicant's amendment filed 27 May 2003, Claims 4 to 10 were amended to make them solely dependent on Claim 1.

In Paragraph 14 the Examiner objects to all claims under 35 U.S.C. 112. Claim 1 has been revised for clarity, to more clearly point out and distinctly claim the subject matter of the present invention. The amendments and subject matter of Claim 1 are discussed below:

Claim 1 now clearly specifies that the construct claimed comprises a complex having two components, namely a chimeric protein and a recombinant polynucleotide.

Part i) of Claim 1 clearly details the components of the chimeric protein. These components of the chimeric protein are a) a nucleotide binding portion which is the binding domain of a nuclear steroid receptor, and b) a target peptide portion.

Part ii) of Claim 1 clearly details the components of the recombinant polynucleotide and their respective functions. The components of the recombinant polynucleotide are a) a chimeric protein-encoding portion, and b) a nucleotide sequence motif. The "chimeric protein-encoding portion" codes for the chimeric protein of the complex. The "nucleotide sequence motif" is a sequence which is recognised and bound by the nucleotide binding portion of the chimeric protein.

The function of the nucleotide binding portion is to bind to the nucleotide sequence motif, hence binding the chimeric protein to the recombinant nucleotide. Thus the nucleotide

binding portion of the chimeric protein recognises, and binds to, the nucleotide sequence motif of the recombinant polynucleotide. The nucleotide binding portion of the chimeric protein is a binding domain from a nuclear steroid receptor. Nuclear steroid receptors are a family of proteins which avidly and selectively bind to specific nucleic acid sequence motifs.

Thus, the chimeric protein-encoding portion of the recombinant polynucleotide is not bound by the chimeric protein itself. If the chimeric protein-encoding portion of the recombinant polynucleotide were to be left unbound, it would be exposed to potential damage, e.g. chemical or enzymatic cleavage. To mitigate this problem Claim 1 specifies that the chimeric protein-encoding portion of the recombinant polynucleotide is protected by a binding moiety (for example, a protein) which binds in a non-sequence specific manner to polynucleotides. Examples of such proteins, which bind polynucleotides irrespective of their sequence, include certain viral coat proteins, as specified in Claim 3.

To address the Examiner's particular objections Applicant will respond to the specific comments in the order in which they were raised in Paragraph 14:

- The components of the complex are now clearly defined. The manner by which the chimeric protein binds to the recombinant polynucleotide has also been clearly defined; this occurs by the well characterised sequence specific interaction of the binding domain of a nuclear steroid receptor (the nucleotide binding portion of the chimeric protein) with its cognate binding sequence in the nucleotide sequence motif of the recombinant polynucleotide.
- The polynucleotide linker sequence is a linking stretch

of nucleic acids within the chimeric protein-encoding portion of the recombinant polynucleotide. In detail, the linker spans between the nucleotides encoding the nucleotide binding portion to the nucleotides encoding the target peptide portion. This is a well-known technique and is common in the art as a way of linking two portions of a recombinant polynucleotide encoding a chimeric protein.

- The components of the chimeric protein are now clear; the nucleotide binding portion comprises a binding domain of a nuclear steroid receptor.
- The term "chimeric protein-encoding portion" is now clearly defined; it encodes the chimeric protein of the complex.
- Amended Claim 1 makes it clear that it is the nucleotide sequence motif alone that is bound by the chimeric protein; the chimeric protein-encoding portion is not bound by the chimeric protein.
- The degree of binding of the nucleotide-binding portion is simply that conferred by a nuclear steroid receptor for its cognate binding motif. The Examiner's objection is not clearly understood.
- The term "at least" has been removed form Claim 1.
- The term "irrespective of nucleotide sequences" relates to non-specific binding. This has been clarified in Claim 1.
- In amended Claim 1 there is antecedent basis for the term "the recombinant polynucleotide" (at line 3). The term "nucleotide sequence" is now in the general form, as it is no longer preceded by the definite article. Reference is made to "a binding moiety" on line 23 of amended Claim 1 and this provides antecedent basis for Claim 3.

The Examiner maintained rejection of Claims 1, 5, 6 and 9 under 35 USC 102(b) as being anticipated by Schatz *et al.* Schatz *et al.* describes the production of a recombinant

polynucleotide encoding a chimeric protein having a DNA binding portion and a target portion and also comprising a DNA sequence recognized and bound by the DNA binding portion of the chimeric protein. However, Schatz *et al.* does not refer to a DNA binding portion being a binding domain of a nuclear steroid receptor, as is required in Claim 1 as amended. Hence Schatz *et al.* fails to disclose this specific feature of the claimed invention.

Furthermore, Schatz et al. does not disclose or suggest protection of the chimeric protein-encoding portion of the recombinant polynucleotide by a protein which binds in a non-sequence specific manner. By contrast, amended Claim 1 clearly recites that a chimeric protein-encoding portion of the recombinant protein (which is not bound by the chimeric protein itself), is protected by a binding moiety (for example a viral protein). As Schatz *et al.* discloses no such binding moiety it does not anticipate Claim 1.

The presence of the non-sequence specific binding moiety provides protection of the full length of the recombinant nucleotide, increasing its robustness and utility.

The Applicant believes that the present Application, as amended, is in a condition for allowance, and issuance of notification to that effect is earnestly solicited.

Respectfully submitted,

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